

SECTION 1

INTRODUCTION

1.1 HISTORICAL PERSPECTIVE

Contamination of aquatic resources, including freshwater, estuarine, and marine fish and shellfish, has been documented in the scientific literature for many regions of the United States (NAS, 1991). Environmental concentrations of some pollutants have decreased over the past 20 years as a result of better water quality management practices. However, environmental concentrations of other heavy metals, pesticides, and toxic organic compounds have increased due to intensifying urbanization, industrial development, and use of new agricultural chemicals. Our Nation's waterbodies are among the ultimate repositories of pollutants released from these activities. Pollutants come from permitted point source discharges (e.g., industrial and municipal facilities), accidental spill events, and nonpoint sources (e.g., agricultural practices, resource extraction, urban runoff, in-place sediment contamination, ground water recharge, and atmospheric deposition).

Once these toxic contaminants reach surface waters, they may concentrate through aquatic food chains and bioaccumulate in fish and shellfish tissues. Aquatic organisms may bioaccumulate environmental contaminants to more than 1,000,000 times the concentrations detected in the water column (U.S. EPA, 1992c, 1992d). Thus, fish and shellfish tissue monitoring serves as an important indicator of contaminated sediments and water quality problems, and many States routinely conduct chemical contaminant analyses of fish and shellfish tissues as part of their comprehensive water quality monitoring programs (Cunningham and Whitaker, 1989). Tissue contaminant monitoring also enables State agencies to detect levels of contamination in fish and shellfish tissue that may be harmful to human consumers. If States conclude that consumption of chemically contaminated fish and shellfish poses an unacceptable human health risk, they may issue local fish consumption advisories or bans for specific waterbodies and specific fish and shellfish species for specific populations.

In 1989, the American Fisheries Society (AFS), at the request of the U.S. Environmental Protection Agency (EPA), conducted a survey of State fish and shellfish consumption advisory practices. Questionnaires were sent to health departments, fisheries agencies, and water quality/environmental management departments in all 50 States and the District of Columbia. Officials in all 50 States and the District responded.

Respondents were asked to provide information on several issues including

- Agency responsibilities
- Sampling strategies
- Sample collection procedures
- Chemical residue analysis procedures
- Risk assessment methodologies
- Data interpretation and advisory development
- State concerns
- Recommendations for Federal assistance.

Cunningham et al. (1990) summarized the survey responses and reported that monitoring and risk assessment procedures used by States in their fish and shellfish advisory programs varied widely. States responded to the question concerning assistance from the Federal government by requesting that Federal agencies

- Provide a consistent approach for State agencies to use in assessing health risks from consumption of chemically contaminated fish and shellfish
- Develop guidance on sample collection procedures
- Develop and/or endorse uniform, cost-effective analytical methods for quantitation of contaminants
- Establish a quality assurance (QA) program that includes use of certified reference materials for chemical analyses.

In March 1991, the National Academy of Sciences (NAS) published a report entitled *Seafood Safety* (NAS, 1991) that reviewed the nature and extent of public health risks associated with seafood consumption and examined the scope and adequacy of current seafood safety programs. After reviewing over 150 reports and publications on seafood contamination, the NAS Institute of Medicine concluded that high concentrations of chemical contaminants exist in various fish species in a number of locations in the country. The report noted that the fish monitoring data available in national and regional studies had two major shortcomings that affected their usefulness in assessing human health risks:

- In some of the more extensive studies, analyses were performed on nonedible portions of finfish (e.g., liver tissue) or on whole fish, which precludes accurate determination of human exposures.
- Studies did not use consistent methods of data reporting (e.g., both geometric and arithmetic means were reported in different studies) or failed to report crucial information on sample size, percent lipid, mean values of contaminant concentrations, or fish size, thus precluding direct comparison of the data from different studies and complicating further statistical analysis and risk assessment.

As a result of these NAS concerns and State concerns expressed in the AFS survey, the EPA Office of Water established a Fish Contaminant Workgroup. It is composed of representatives from EPA and the following State and Federal agencies:

- U.S. Food and Drug Administration (FDA)

- U.S. Fish and Wildlife Service (FWS)
- Ohio River Valley Water Sanitation Commission (ORSANCO)
- National Oceanic and Atmospheric Administration (NOAA)
- Tennessee Valley Authority (TVA)
- United States Geological Survey (USGS)

and representatives from 26 States: Alabama, Arkansas, California, Colorado, Delaware, Florida, Georgia, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Nebraska, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oregon, Texas, Virginia, and Wisconsin.

The objective of the EPA Fish Contaminant Workgroup was to formulate guidance for States on how to sample and analyze chemical contaminants in fish and shellfish where the primary end uses of the data included development of fish consumption advisories. The Workgroup compiled documents describing protocols currently used by various Federal agencies, EPA Regional offices, and States that have extensive experience in fish contaminant monitoring. Using these documents, they selected methods considered most cost-effective and scientifically sound for sampling and analyzing fish and shellfish tissues. These methods are recommended as standard procedures for use by the States and are described in this manual.

1.2 PURPOSE

The purpose of this manual is to provide overall guidance to States on methods for sampling and analyzing contaminants in fish and shellfish tissue that will promote consistency in the data States use to determine the need for fish consumption advisories. **This manual provides guidance only and does not constitute a regulatory requirement for the States.** It is intended to describe what the EPA Office of Water believes to be scientifically sound methods for sample collection, chemical analyses, and statistical analyses of fish and shellfish tissue contaminant data for use in fish contaminant monitoring programs that have as their objective the protection of public health. This nonregulatory, technical guidance manual is intended for use as a handbook by State and local agencies that are responsible for sampling and analyzing fish and shellfish tissue. Adherence to this guidance will enhance the comparability of fish and shellfish contaminant data, especially in interstate waters, and thus provide more standardized information on fish contamination problems.

In order to enhance the use of this guidance as a working document, the EPA will issue additional information and updates to users as appropriate. It is anticipated that updates will include minor revisions such as the addition or deletion of chemicals from the recommended list of target analytes, new screening values as new toxicologic data become available, and new chemical analysis procedures for some target analytes as they are developed. A new edition of the guidance will be issued to include the addition of major new areas of guidance such as using frogs and waterfowl as target species for assessment of human health risks or when major changes are made to the Agency's risk assessment procedures.

The EPA Office of Water realizes that adoption of these recommended methods requires adequate funding. In practice, funding varies among States and resource limitations will cause States to tailor their fish and shellfish contaminant monitoring

programs to meet their own needs. States must consider tradeoffs among the various parameters when developing their fish contaminant monitoring programs. These parameters include

- Total number of stations sampled
- Intensity of sampling at each site
- Number of chemical analyses and their cost
- Resources expended on data storage and analysis, QA and quality control (QC), and sample archiving.

These tradeoffs will limit the number of sites sampled, number of target analytes analyzed at each site, number of target species collected, and number of replicate samples of each target species collected at each site (Crawford and Luoma, 1993).

1.3 OBJECTIVES

The specific objectives of the manual are to

1. Recommend a tiered monitoring strategy designed to
 - Screen waterbodies (**Tier 1**) to identify those harvested sites where chemical contaminant concentrations in the edible portions of fish and shellfish exceed human consumption levels of potential concern (screening values [**SVs**]). SVs for contaminants with carcinogenic effects are calculated based on selection of an acceptable cancer risk level. SVs for contaminants with noncarcinogenic effects are concentrations determined to be without appreciable noncancer health risk. For a contaminant with both carcinogenic and noncarcinogenic effects, the lower (more conservative) of the two calculated SVs is used.
 - Conduct intensive followup sampling (**Tier 2, Phase I**) to determine the magnitude of the contamination in edible portions of fish and shellfish species commonly consumed by humans in waterbodies identified in the screening process.
 - Conduct intensive sampling at additional sites (**Tier 2, Phase II**) in a waterbody where screening values were exceeded to determine the geographic extent of contamination in various size classes of fish and shellfish.
2. Recommend target species and criteria for selecting additional species if the recommended target species are not present at a site.
3. Recommend target analytes to be analyzed in fish and shellfish tissue and criteria for selecting additional analytes.

4. Recommend risk-based procedures for calculating target analyte screening values.
5. Recommend standard field procedures including
 - Site selection
 - Sampling time
 - Sample type and number of replicates
 - Sample collection procedures including sampling equipment
 - Field recordkeeping and chain of custody
 - Sample processing, preservation, and shipping.
6. Recommend cost-effective, technically sound analytical methods and associated QA and QC procedures, including identification of
 - Analytical methods for target analytes with detection limits capable of measuring tissue concentrations at or below SVs
 - Sources of recommended certified reference materials
 - Federal agencies currently conducting QA interlaboratory comparison programs.
7. Recommend procedures for data analysis and reporting of fish and shellfish contaminant data.
8. Recommend QA and QC procedures for all phases of the monitoring program and provide guidance for documenting QA and QC requirements in a QA plan or in a combined work/QA project plan.

1.4 RELATIONSHIP OF MANUAL TO OTHER GUIDANCE DOCUMENTS

This manual is the first in a series of four documents to be prepared by the EPA Office of Water as part of a Federal Assistance Plan to help States standardize fish consumption advisories. This series of four documents—Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories includes

- Volume I: Fish Sampling and Analysis (EPA 823-R-93-00), published August 1993
- Volume II: Risk Assessment and Fish Consumption Limits (EPA 823-B-94-004), published June 1994
- Volume III: Risk Management, to be published in FY 1996
- Volume IV: Risk Communication (EPA 823-R-95-001), published March 1995.

This sampling and analysis manual is not intended to be an exhaustive guide to all aspects of sampling, statistical design, development of risk-based screening values, laboratory analyses, and QA and QC considerations for fish and shellfish

contaminant monitoring programs. Key references are provided that detail various aspects of these topics.

In addition, interested individuals may obtain a software program (on five 3.5-inch diskettes) of all fish consumption advisories for the 50 States and U.S. Territory waters entitled *The National Listing of Fish Consumption Advisories* (EPA-823-C-95-001) by contacting:

U.S. Environmental Protection Agency
National Center for Environmental Publications and Information
11029 Kenwood Road
Cincinnati, OH 45242
(513) 489-8190

In October 1995, EPA also will make this database available for downloading from the Internet. Point your World Wide Web browser to the following URL:

<http://www.epa.gov/water>

1.5 ORGANIZATION OF THIS MANUAL

This manual provides specific guidance on sampling, chemical analysis, and data reporting and analysis procedures for State fish and shellfish contaminant monitoring programs. Appropriate QA and QC considerations are integral parts of each of the recommended procedures.

Monitoring Strategy: Section 2 outlines the recommended strategy for State fish and shellfish contaminant monitoring programs. This strategy is designed to (1) routinely screen waterbodies to identify those locations where chemical contaminants in edible portions of fish and shellfish exceed human health screening values and (2) sample more intensively those waterbodies where exceedances of these SVs have been found in order to assess the magnitude and the geographic extent of the contamination.

Target Species: Section 3 discusses the purpose of using target species and criteria for selection of target species for both screening and intensive studies. Lists of recommended target species are provided for inland fresh waters, Great Lakes waters, and seven distinct estuarine and coastal marine regions of the United States.

Target Analytes: Section 4 presents a list of recommended target analytes to be considered for inclusion in screening studies and discusses criteria used in selecting these analytes.

Screening Values: Section 5 describes the EPA risk-based procedure for calculating screening values for target analytes.

Field Procedures: Section 6 recommends field procedures to be followed from the time fish or shellfish samples are collected until they are delivered to the laboratory for processing and analysis. Guidance is provided on site selection and sample collection procedures; the guidance addresses material and equipment

requirements, time of sampling, size of animals to be collected, sample type, and number of samples. Sample identification, handling, preservation, shipping, and storage procedures are also described.

Laboratory Procedures: Section 7 describes recommended laboratory procedures for sample handling including: sample measurements, sample processing procedures, and sample preservation and storage procedures. Section 8 presents recommended laboratory procedures for sample analyses, including cost-effective analytical methods and associated QC procedures, and information on sources of certified reference materials and Federal agencies currently conducting interlaboratory comparison programs.

Data Analysis and Reporting: Section 9 includes procedures for data analysis to determine the need for additional monitoring and risk assessment and for data reporting. This section also describes the National Fish Tissue Data Repository (NFTDR), a national database of fish and shellfish contaminant monitoring data.

Supporting documentation for this guidance is provided in Section 10, Literature Cited, and in Appendixes A through M.